K000861

OCT 3 0 2000

510(k) Summary

Submitter

Gillette Children's Specialty Healthcare
200 East University Avenue
St. Paul, MN 55101

Telephone: (651) 229-3800
Fax: (651) 229-3965

Name of Device

CranioCap™ Cranial Orthosis

Predicate Device

Dynamic Orthotic Cranioplasty – DOC™ Band

Device Description

The CranioCap™ is a cranial orthosis for the treatment of deformational plagiocephaly. It is a light-weight, semi-rigid plastic helmet. Pads are placed inside to create a fit that is snug in some areas and recessed in others. As the brain grows, the skull is slowly redirected into the recessed areas, thereby gradually rounding the skull.

Intended Use

The CranioCap™ is intended for use on infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, bradycephalic-, and scaphocephalic-shaped heads.

Technological Characteristics

Since each child with deformational plagiocephaly presents with a unique head size and affected area(s) of the head, each CranioCap™ is custom-fabricated. CranioCap™ fabrication begins with a plaster impression (mold) of the child's head. From this impression, a plaster model of the baby's head is made. From that model, a light-weight plastic helmet is made. The CranioCap™ liner is inserted into the helmet. This liner is designed to fit snugly in some areas and is recessed in others. As the baby's brain grows, the skull growth is redirected into the recessed areas of the orthosis, rounding the skull over time.

Summary of Studies

Information was provided on the biocompatibility of the materials and the safety and effectiveness of helmet therapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2000

Ms. Linda Valeri
Manager, Assistive Technology Department
Gillette Children's Specialty Healthcare
c/o Regulatory & Clinical Research Institute, Inc.
200 East University Avenue
Saint Paul, Minnesota 55101

Re: K000861
Trade Name: Craniocap
Regulatory Class: II
Product Code: MVA
Dated: July 27, 2000
Received: August 1, 2000

Dear Ms. Valeri:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): N/A K000861

Device Name: CranioCap™

Indications for Use: The CranioCap™ is intended for use on infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads. The device is intended to apply passive pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____

(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K000861